

# Pharma Data Integrity Summit

26<sup>th</sup> June 2019 | 09:30 to 17:00 Hrs  
Hotel Satkar Residency, Thane (W)



This is one of the #100 Knowledge Sharing Events that Anton Paar India is conducting on the occasion of its 10<sup>th</sup> year anniversary.

## About this summit:

Data Integrity is one of the most demanding topics that regulated industries like pharmaceuticals have to deal and comply with on a continued basis.

This industry-focussed event seeks to offer a knowledge sharing platform for pharma professionals to learn in-depth about regulatory requirements, industry best practices and applying these in a real world environment. The summit includes training sessions, panel discussions and keynote presentations from industry experts.

Topics	Speaker	Time
<b>Training Session :</b>  <b>Avoiding data integrity related issues by implementing best practices in system design, monitoring and control</b>  <ul style="list-style-type: none"> <li>- GxP Work flow Control</li> <li>- SDLC Life Cycle Control</li> <li>- Data Life Cycle control</li> <li>- Using GAMP5 Drivers, CFR Part11 and Annex 11 to prevent, detect and eliminate Data Integrity related issues.</li> <li>- Audit Citations and Remediation to 483 and Warning letters</li> </ul>	<b>Mr. Kalpesh Vaghela</b> CEO, Infra Control Systems	09:30 – 13:00
<b>Lunch Break</b>		13:00 – 14:00
<b>Analytical Measurements : #IntegrityByDesign</b>	<b>Dr. Nils Bertram</b> CEO, Anton Paar OptoTec GmbH	14:00 – 14:30
<b>Keynote Presentation :</b>  <b>General Principles of Periodic Review of Validated Systems</b>	<b>Mr. Srinivasa Reddy</b> Corporate Quality Head, Electronic Data Compliance, Lupin	14:30 – 15:00
<b>Keynote Presentation :</b>  <b>Laboratory Automation – Making Laboratory Paperless</b>	<b>Mr. Milind Gujar</b> Chief Quality Officer, RPG Life Sciences	15:00 – 15:30
<b>Tea/Coffee Break</b>		15:30 – 16:00
<b>Expert Panel Discussion :</b>  <b>Upcoming Trends in Data Governance Systems</b>	Moderated by : Mr. Kalpesh Vaghela	16:00 – 16:30
<b>Question and Answer Session</b>		16:30 – 17:00

## Speakers:



**Mr. Kalpesh R. Vaghela** has 33 years of experience as automation and software validation specialist. He has attained expertise as a trainer on topics like CSV- Data Integrity, GAMP5,

21 CFR Part 11 compliance, ICH Q9 risk assessment, proactive CSV approach, Annex11, GDPR. Since the last two decades, Mr. Vaghela has been helping Indian and International pharmaceutical companies achieve compliance. He is currently the CEO of Infra Control Systems.



**Dr. Nils Bertram** is a Doctorate in Physics and currently heads Anton Paar OptoTec GmbH in Hanover, Germany as the CEO. Having worked for the pharmaceutical market for nearly a decade, he has

experienced the evolution of compliance requirements where anticipating the market need and transforming it into most suitable instrument and software design is crucial.



**Mr. Srinivasa Reddy** has more than 23 years of functional experience in Pharmaceutical and IT industry with exposure on verticals like Electronic Data Compliance w.r.t Part-11,

Annex-11, Annex-5, GAMP5, ISO, ASTM E2500, software development and implementation, QMS, CSLCM, QRM, GLP & GCP environments. He is currently working as the Corporate Quality Head, Electronic Data Compliance, Lupin.



**Mr. Milind Gujar** has rich experience of around 29 years in Quality Management of Pharma Formulations & API with reputed pharmaceutical companies like Emcure, Micro Labs, Reliance Life

Sciences, Cipla and Ipca Laboratories Limited. He is currently working as the Chief Quality Officer with RPG Life Sciences.

Click here to [register](#) for the summit.

To know more, contact:

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We look forward to welcoming you at the summit.

With best regards,

Anton Paar India